Immunocept, LLC, et al v. Fulbright & Jaworski Doc. 57

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

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WESTERN DISTRICT OF TEXAS
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IMMUNOCEPT, LLC, PATRICE ANNE LEE, AND JAMES REESE MATSON,	§	
	§	
Plaintiffs,	§	
	§	
vs.	§	CAUSE NO. A 05 CA 334 SS
	§	
FULBRIGHT & JAWORSKI, LLP,	§	
	§	
Fulbright.	§	

PLAINTIFFS' MOTION FOR JUDGMENT CONCERNING THE LEGAL INTERPRETATION OF CERTAIN CLAIM LANGUAGE

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I
INTRODUCTION

In this patent malpractice case, plaintiff Immunocept alleges that defendant Fulbright & Jaworksi ("Fulbright") negligently prosecuted a patent that was intended to cover Immunocept's new approach for treating sepsis. The outcome of this action depends critically upon three purely legal issues of patent claim interpretation that Immunocept asks the Court to resolve before trial. The first issue is at the heart of this case: whether, as a matter of law, the patent was so narrowly drafted by Fulbright that it permits others to use Immunocept's technique with impunity merely by combining it with any other sepsis treatment. The next legal question is whether Fulbright had the ability to transform claim "preamble" language into effective claim limitations, by submitting arguments to the Patent Examiner that rely upon the preamble as if it were limiting. Finally, Immunocept asks the Court to confirm that the terms "blood" and "whole blood" as used in the claim carry the plain meaning that practitioners in this field would expect, namely, blood as drawn from the body, and not plasma or other products that could be made from blood. Each of these issues is ripe for determination by the Court before trial, and requires resolution since the course and conduct of the trial will depend critically on the Court's decisions.

II
FACTUAL BACKGROUND

In the 1990s, plaintiffs Drs. James Matson and Patrice Lee developed large pore hemofiltration technology for the treatment for sepsis, a condition that kills more than one hundred thousand people each year in the United States. Immunocept's large pore hemofiltration technology treats sepsis by removing potentially fatally excessive "toxic mediators" from a patient's blood stream.

Immunocept asked Fulbright to file a patent application that would protect its large pore hemofiltration technology. When the original attorney handling the Immunocept patent application quit the firm, Fulbright reassigned the application to Sarah Brashears, a junior associate a few months out of law school whose only formal patent training was a single patent review course.

After taking responsibility for the application, Ms. Brashears amended the application by inserting the words "consisting of" in the claim 1, thereby limiting the scope of the claim to treatments for toxic mediator-related diseases (such as sepsis) in which hemofiltration is the *only* step, and forfeiting patent protection for any treatment that combines this filtration with any other step for treating the disease.

The term "consisting of" limits a method claim so that it covers *only* the step(s) recited in the claim.[1] Thus, a competitor can easily design a process that avoids infringement simply by adding to the process any step not recited in the claim. For example, if a claim recites a method for improving the appearance of a car "consisting of" two steps – (1) applying a soap solution to the car, and (2) rinsing the car – then a competitor who wishes to perform these same steps can avoid infringement merely by adding a drying or waxing step to the process. Such a process does not "consist of" the two recited steps because it also includes a third unclaimed step, drying or waxing, and the patent owner then has *no recourse* against this competitor.

For this reason, patent lawyers studiously avoid using the words "consisting of" in favor of the open ended transitional phrase "comprising." A method claim that uses the transitional phrase "comprising" includes but is not limited to the step(s) recited in the claim.[2] If in the above example "comprising" were substituted for "consisting of", the addition of a drying or waxing step would therefore *not* escape the claim, and the claim would have radically broader scope. Thus, the unnecessary insertion of "consisting of" into the Immunocept's patent claim worked a drastic narrowing of the patent scope and a consequent loss of value that underlies this action.

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[1] *See*, Manual of Patent Examining Procedure ("MPEP") at § 2111.03 (Rev. 4 Oct. 2005) (attached as Exh. A to Fielding Declaration); Chisum On Patents (Release 82 March 2002) at 8.06[1][b][ii][B] (attached as Exh. B).

[2] *See*, MPEP § 2111.03; Chisum at §8.06[1][b][ii][A] and [B].

The second issue before the Court arises not from amendments to the claim but from arguments that were or could have been made about its contents. The law is clear that applicants may choose to present arguments to the Examiner, relying upon language in the preamble of a claim to distinguish prior art, that have the effect of transforming the preamble into claim limitations. During prosecution of the patent, Fulbright did just that, when faced a rejection of the claim based upon U.S. Patent No. 4,874,522 to Okamoto, in which the Examiner asserted that Okamoto disclosed the essence of Immunocept's invention. In response, Fulbright argued that Okamoto differed from the claim by not addressing "sepsis, shock or multiorgan system failure," that is, "toxic mediator-related diseases" as set out in the preamble of Immunocept's claim. Fulbright could have chosen to make such arguments at any time, and did so for Okamoto. As will be shown below, such arguments made to obtain a patent are binding on the patentee, making the preamble limiting for all purposes, both when considering other prior art references during prosecution and when the issued patent claim is to be interpreted, as it must be for this action to proceed.

The third and final issue presented in this motion arises from the use the terms "blood" and "whole blood" in the claim, consistent with the ordinary usage of these terms in the field and with their use throughout the specification of the patent as they would be interpreted by workers in the field. In that context, it is clear that these terms refer to blood as drawn from the body, in contrast to other derivatives or products that might be made from such blood by removing cells, removing plasma, or other operations. Immunocept asks the Court to confirm this simple fact.

III
Legal Analysis

A. The Legal Standards for Claim Interpretation.

Claim interpretation is an issue of law to be resolved by the Court, not the jury.[3] Courts now commonly resolve disputes over the meaning of claims prior to trial.[4] To construe claims, the Court examines the "intrinsic evidence," which consists of the literal language of the claims, the patent's specification and its prosecution history.[5] It is well established that the intrinsic record is the primary source for determining a claim's meaning.[6] In fact, the claims can often be interpreted from the intrinsic record alone, without any "extrinsic" evidence such as testimony from experts in the field. Given the nature of the claim interpretation issues presented here, the Court requires only the intrinsic record, as will be apparent from the discussion below.

B. The Claim is Limited to a Single Step Method.

The claim at issue is reproduced below:

Preamble	A method of treating a pathophysiological state caused by a toxic mediator-related disease
Transition	*consisting of*:
Body	Hemofiltering blood with a filter, wherein said filter has a molecular weight exclusion limit of 100,000 to 150,000 daltons and allows for passage of molecules with a molecular weight of about 70,000 daltons in the presence of whole blood.

[3] *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1996) (en banc), aff'd, 517 U.S. 370 (1996).

[4] *EMI Group North America Inc. v. Intel Corp.*, 157 F.3d 887 (Fed. Cir. 1998) ("Construction of claims by the trial court is often concluded upon a preliminary evidentiary hearing called a Markman hearing in homage to the decision cited supra that establishes that this step must be performed by the Judge, not the jury."); *Goldtouch Technologies Inc. v. Microsoft Corporation*, 2000 U.S. Dist. Lexis 3370 (W.D. Tx 2000).

[5] *Deering Precision Instruments v. Vector Distributions Systems. Inc.*, 347 F.3d 1314, 1322 (Fed. Cir. 2003).

[6] *Phillips v. AWH Corp, et al.*, 415 F.3d 1303 (Fed. Cir. 2005).; *Astrazeneca AB et. al. Mutual Pharmaceutical Co., Inc.*, 384 F.3d 1333, 1336-1337 (Fed. Cir. 2004) *citing Bell Atl. Network Servs., Inc. v. Covad Communications Group, Inc.*, 262 F.3d 1258, 1268 (Fed. Cir. 2001); *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996); *Autogiro Co. of Am. v. United States*, 384 F.2d 391, 397-98 (Ct. Cl. 1967).

As shown, the claim includes three parts: 1) a preamble, 2) a transition, and 3) a body. The preamble states that the claim is directed to a method for treating a medical condition, in particular, a "pathophysiological state caused by a toxic mediator-related disease." As explained in the specification, sepsis is an example of the condition recited in the preamble.

The transition portion says that the claimed method "consists of" the step(s) recited in the body of the claim, here a single hemofiltration filtration step. The legal meaning of the transition "consisting of" is well established and seems beyond dispute. As explained by the Court of Appeals for the Federal Circuit, the meaning of "consisting of" is best understood by comparison to the widely preferred transition "comprising":

> The phrase "consisting of" is a term of art in patent law signifying restriction and exclusion, while in contrast, the term "comprising" indicates an open ended construction. (Citation omitted). In simple terms, a drafter uses the phrase 'consisting of' to mean 'I claim what follows and nothing else.' A drafter uses the term 'comprising' to mean 'I claim at least what follows and potentially more.'[7]

Similarly, the patent office's Manual of Patent Examining Procedure explains that "consisting of" limits the claim to the specific steps that follow and nothing more:

> The transitional phrases "comprising .... and "consisting of" define the scope of a claim with respect to what unrecited additional components or steps, if any, are excluded from the claim.
>
> The transitional term "comprising," which is synonymous with "including," "containing", or "characterized by," is inclusive or open ended and does not exclude additional unrecited elements or method steps . . ..
>
> The transitional phrase "consisting of" excludes any element, step or ingredient not specified in the claim." MPEP § 2111.03 (citations omitted).

Indeed, "consisting of" is so limiting that Landis' treatise on claim drafting advises practitioners to avoid this language:

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[7] *Vehicular Technologies Corp. v. Titan Wheel International*, 212 F.3d 1377 (Fed. Cir. 2000).

> "Consisting of" ... means that the claim covers devices having the recited elements, *and no more*, and in method claims, means that the process has *only* the recited steps. ...
>
> [Claims with this language] are spoken of as "closed" or "closed ended" because other elements or other material elements are excluded from the combination. Of course, "consisting" *should be avoided* in the broader claims wherever possible as it is severely limiting. *Landis* at § 8 (attached as Exhibit C)(footnotes omitted, emphasis added).

Thus, the gratuitous insertion of "consisting of" narrowed the claim to a treatment that has one and only one step – the hemofiltration step recited in the body of the claim. Fulbright thereby forfeited coverage of *multi-step* treatments that combine filtration with *any* additional step for treating the condition. Had the attorney instead used the commonly preferred transition "comprising", the claim would have encompassed multi-step treatments that include Immunocept's hemofiltration technique.

C. The Preamble of Claim 1 is Limiting.

The preamble of claim 1 states: "A method of treating a pathophysiological state caused by a toxic mediator-related disease." The claim construction issue addressed here relates to whether the preamble language is a limitation that could have been used to distinguish a prior art reference. In *Catalina Marketing, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002), the Federal Circuit explained the general principles used to decide if a claim's preamble is limiting:

> In general, a preamble limits the invention if it recites essential structure or steps, or if it is "necessary to give life, meaning, and vitality" to the claim. *Pitney Bowes*, 182 F.3d at 1305. Conversely, a preamble is not limiting "where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention." *Rowe v. Dror*, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997).

The Court in *Catalina Marketing* went on to explain that a claim's preamble will always be limiting *if the applicant argues that it is during prosecution of the patent*:

> ...[C]lear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art transforms the preamble into a claim limitation because such reliance indicates use of the preamble to define, in part, the claimed invention.[8]

Thus, at any time during prosecution of the '418 patent, Fulbright had the ability to give limiting effect to the preamble merely by arguing that its content provides a distinction over any prior art then of concern. Indeed, Fulbright recognized and explicitly exercised that option and transformed the preamble to a limitation. When confronted with a rejection based upon the prior art Patent 4,874,522 to Okamoto et al., Fulbright argued that Okamoto did not teach treatment for "sepsis, shock or multiorgan system failure" – all of which are "toxic mediator-related diseases," the language recited in the preamble of claim 1.[9] The June 17, 1996 Response states in part:

> Finally, the Examiner states that 'Okamoto et al. disclose a method of continuous arteriovenous hemofiltration of animals with microglobulin which may cause sepsis, shock or multiorgan system failure." Applicants contend that, contrary to the Examiner's statement, B2MG [microglobulin] has no known role in sepsis, shock or multiorgan system failure. As stated in the declarations of Drs. Lee and Matson, their clinical and research work has focused on sepsis, shock, SIRS and multiorgan system failure; however, they know of no causal association between B2MG and sepsis, septic shock, SIRS or MOSF, nor are they aware that such an association exists.... Thus, Applicants contend that Okamoto et al. does not teach or suggest a method of continuous arteriovenous hemofiltration to treat sepsis, shock, or multiorgan system failure. (Response at p. 4, attached as Exhibit D).

Clearly, Fulbright knew that it could rely on preamble language to overcome prior art rejections. Fulbright's choice to use it to distinguish the prior art Okamoto et al. patent during prosecution of the '418 patent confirms that the preamble could have been and in fact was treated as a limitation here. *Catalina Marketing*, 289 F.3d at 808. As a limitation, it restricts the scope of the claim for all purposes, whether as a supporting basis for distinguishing the Okamoto prior art, as a basis for potential arguments that could have been made to distinguish other prior art, or as a basis for determining whether a later method infringes.

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[8] *Id.* (citing *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.* 246 F.3d 1368, 1375 (Fed. Cir. 2001).

[9] The '418 patent at 1:19-39 states: "Medical illness, trauma, ... i.e., any human disease state, if sufficiently injurious to the patient, may elicit the Systemic Inflammatory Response Syndrome (SIRS)... . If the stimulus to SIRS is too potent, e.g., as a result of massive tissue injury or microbial sepsis, then the SIRS may be extreme. The resulting excessive inflammation is injurious or destructive to vital organ tissue resulting in vital organ dysfunction or failure. This is recognized clinically as multi-organ system failure (MOSF).... The mechanism of SIRS is the excessive release of host derived inflammatory mediators, referred to in this context as toxic mediators (TM)."

D. "Blood" and "Whole Blood" Mean Blood as Drawn from the Body.

Claim 1 of the '418 patent is reproduced again below:

> 1. A method of treating a pathophysiological state caused by a toxic mediator-related disease consisting of hemofiltering *blood* with a filter, wherein said filter has a molecular weight exclusion limit of 100,000 to 150,000 Daltons and allows for passage of molecules with a molecular weight of about 70,000 Daltons *in the presence of whole blood.*

Immunocept asks the Court to construe the terms "blood" and "whole blood" to mean "blood as drawn from the body." This is the meaning used in the specification of the '418 patent, and it is distinct from blood that has been processed to remove most or all of one component, such as plasma (the liquid component of blood from which most of the blood cells have been removed) or packed blood cells (from which most of the plasma has been removed).

Again, the claim relates to the step of "hemofiltering blood with a filter." Hemofiltration is generally described in the specification of the '418 patent at 2:27-33 as follows:

> The hemofilter is part of a blood circuit. In passive flow HF, arterial blood flows through a large bore cannula, into plastic tubing leading to the filter; blood returns from the filter through plastic tubing to a vein. This is known as arteriovenous HF. Alternately, a blood pump is used so that blood is pumped from a vein to the filter and returned to a vein or venovenous HF.

And at 4:17-22, the specification of the '418 patent states:

> ...the term "Extracorporeal Circuit" refers to the system of plastic tubes attached to the hemofilter which is used clinically. The arterial line is the plastic tube which carries blood from artery or vein to the blood inlet port of the hemofilter. The venous line carries blood from the blood outlet port returning to a vein.

As the *en banc* Federal Circuit recently stated in *Phillips v. AWH Corp.*, "[i]t is a 'bedrock principle' of patent law that 'the claims of a patent define the invention to which the patentee is entitled the right to exclude.'"[10] Therefore, a claim construction analysis must begin with the words of the claim.[11] The words of the claim are generally given their ordinary and customary meaning,[12] which "is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention."[13] Since the person of ordinary skill in the art views the claim term in the light of the entire intrinsic record, the claims "must be read in view of the specification, of which they are a part."[14] Finally, "The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction."[15]

Both the claim language and the specification of the '418 patent are consistent: the blood that is filtered is blood as it is drawn from the body; and the filter is designed such that it "allows for passage of molecules with a molecular weight of about 70,000 Daltons *in the presence of whole blood*" – again, blood as it is drawn from the body.[16] Moreover, this is a case in which:

> [T]he ordinary meaning of claim language as understood by a person of skill in the art [is] readily apparent even to lay judges, and claim construction [thus] involves little more than the application of the widely accepted meaning of commonly understood words.[17]

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[10] *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004)).

[11] *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996).

[12] *Id.*, at 1582.

[13] *Phillips*, 415 F.3d at 1313.

[14] *Markman*, 52 F.3d at 979.

[15] *Phillips*, 415 F.3d at 1316 (quoting *Renishaw PLC v. Marposs Societá per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998)).

[16] *See also*, 4:25-31.

[17] *Phillips*, 415 F.3d at 1314.

The terms "blood" and "whole blood" in claim 1 should therefore be construed to mean "blood as drawn from the body."

IV
CONCLUSION

Accordingly, Immunocept asks the Court to rule as a matter of law that in claim 1 of the '418 patent, the term "consisting of" limits the claim to a one step process for treating a pathophysiological state caused by toxic mediators. That step is the specific hemofiltration step recited in the body of the claim. If any additional steps are used to treat a pathophysiological state caused by toxic mediators together with the hemofiltration step, the claim would not cover that method. Furthermore, Fulbright's reliance upon the preamble of the claim to obtain issuance of the patent shows that it had the ability to, and in fact did, make the preamble language limiting for purposes of claim interpretation. Finally, the terms "blood" and "whole blood" mean exactly that – blood as drawn from the body, and not plasma or other blood-related products.

Respectfully submitted,

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CERTIFICATE OF CONFERENCE

Counsel for movant and counsel for respondent have personally conducted a conference at which there was a substantive discussion of every item presented to the Court in this motion and despite best efforts the counsel have not been able to resolve those matters presented.

Certified to the 21st day of February, 2006, by

Jeremy A. Fielding

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the above and foregoing document has been served as shown below on this the 21st day of February, 2006:

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